ISMPP University

The program will begin promptly at 11am EDT

October 25, 2017
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ISMPP Announcements


• The ISMPP U Committee wants to hear from you! Groups or individual members can submit topic ideas via the ISMPP U proposal form located on the ISMPP U Committee page: http://www.ismpp.org/ismppu
To optimize your webinar experience today:

• Use a hardwired connection if available
• Use the fastest internet connection available to you
• If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers
Questions

• To ask a question, please type your query into the Q&A box

• To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "ALL Panelists" Otherwise, all audience members will be able to see your submitted question

• We will make every effort to respond to all questions

NOTE: Make sure you send your question to “ALL Panelists”
**FACULTY: Theodora (Theo) Bloom** is executive editor of *The BMJ* (since 2014) and was European Coordinator for the 8th Peer Review Congress. At *The BMJ* her responsibilities include operations in print and online, as well as ethical and policy matters. She has worked in biomedical publishing since 1992, initially as an editor on the biology team at *Nature*, and then on the founding team of *Current Biology*. After a number of years helping to develop *Current Biology* and its siblings *Structure and Chemistry & Biology*, Theo joined the beginnings of the open access movement. As the founding editor of *Genome Biology* she was closely involved in the birth of the commercial open access publisher BioMed Central, where she remained for several years, ultimately as Editorial Director for *Biology*. After a spell as a freelance publishing consultant working with a variety of clients, including a medical communications agency, she joined the non-profit open access publisher Public Library of Science (PLOS) in 2008, first as chief editor of PLOS Biology and later as Biology Editorial Director with additional responsibility for PLOS Computational Biology and PLOS Genetics. She also took the lead for PLOS on issues around data access and availability. She chairs the scientific advisory board for EMBL-EBI Literature Services. Until recently she served on the boards of NAM Publications and the Dryad digital repository, and on the Genome Canada Data Sharing Policies Advisory Committee.

Theo has a bachelor’s degree in Natural Sciences and a PhD in developmental cell biology from the University of Cambridge and worked as a postdoctoral fellow at Harvard Medical School, researching cell-cycle regulation, before moving into publishing.
Introductions

**FACULTY: Jackie Marchington** is Director of Global Operations at Caudex, a McCann Health Company. Jackie joined Caudex in 1990 as a medical editor/writer following a period of post-doctoral research. Since then, she has developed within the company in a range of roles culminating in her current position of Director of Global Operations. During her 25+ years in healthcare communications, she has used her logical approach to problem-solving and project development to evolve the current operating, quality and ethical standards for which Caudex is known.

She develops and delivers both internal and external training on all aspects of medical publications, including publication ethics, compliance and copyright, and works with all Caudex offices to ensure understanding of and adherence to quality control protocols, as well as processes that contribute to the smooth and efficient development of projects. Jackie became a CMPP in 2011, is an active ISMPP committee member (Advocacy and Outreach) and is a member of the Global Alliance of Publication Professionals (GAPP) team, a volunteer group who provide timely and credible responses to influential stories about medical publication professionals (eg, professional medical writers, publication planners).
MODERATOR: Lisa Baker is a freelance medical writer. She was previously a Medical Director at inScience Communications, Springer Healthcare, and a Scientific Team Lead at Envision Pharma Group. Lisa’s work has included publication development and strategic publication planning for varied clients and therapeutic areas. Lisa received her PhD in research psychology from McGill University. She is an ISMPP Certified Medical Publication Professional™ (CMPP) and is the current chair of the ISMPP U Committee.
Learning Objectives

At the end of this presentation attendees should be able to:

• Have an increased awareness of the latest issues surrounding peer review and scientific publications

• Have a summary of the key takeaways from the Eighth International Congress on Peer Review and Scientific Publication

• Be familiar with the implications for publications professionals of the topics discussed at the Peer Review Congress
Disclaimer

Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP.
EIGHTH INTERNATIONAL CONGRESS ON PEER REVIEW AND SCIENTIFIC PUBLICATION HIGHLIGHTS
Theo Bloom
I am currently Executive Editor of *The BMJ*, published by BMJ, a wholly owned subsidiary of the British Medical Association.

*The BMJ* is co-organizer of the Peer Review Congress, and I was European Coordinator this year.

- I previously worked for PLOS, 2008-2014
- Current voluntary role: EBI/Literature Services/EuropePMC Advisory Board
- I’m solely responsible for today’s content
What I’ll talk about today

• From the perspective of a journal editor
• Some work from colleagues and former colleagues
• Most credit to Hilda Bastian, and the twitterati

http://blogs.plos.org/absolutely-maybe
Key disagreements at the Congress

Should publication be ...?

- Single- double- or triple-blind
- Rapid / immediate
- Transparent and open
- Slow and careful
Biases in reporting and in peer review

What types of bias?
Bias #1: Gender

Jory Lerback and Brooks Hansen. American Geophysical Union
Bias #2: Spin

<table>
<thead>
<tr>
<th>Definition</th>
<th>n = 35</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting practices that distort the interpretation of results and create misleading conclusions, suggesting a more favourable result</td>
<td>20 (57%)</td>
<td>&quot;...we take it to mean...&quot;</td>
</tr>
<tr>
<td>Discordance between results and their interpretation, with the interpretation more favourable than the results</td>
<td>9 (26%)</td>
<td>&quot;...we conclude...&quot;</td>
</tr>
<tr>
<td>Attribution of causality when study design does not support it</td>
<td>3 (9%)</td>
<td>&quot;Inappropriate claims given study design&quot;</td>
</tr>
<tr>
<td>Overinterpretation or inappropriate extrapolation of results</td>
<td>3 (9%)</td>
<td>&quot;We do not recommend...&quot;</td>
</tr>
</tbody>
</table>

https://doi.org/10.1371/journal.pbio.2002173.t002

Bias #3: Interim results

Be aware of interim results of randomized trials, says Steven Woloshin #PRC8

Summary

Many interim publications report analyses that are not pre-specified or lack a compelling justification.

Frequent nonpublication may cause bias since final treatment effects remain unknown.

Interim and final publications have similar journal and media prominence but conclusions may change.
Bias #3: Interim results

#prc8 an interim meta meta-analysis. Length of question (in seconds) by who asked the question
12:05 AM - Sep 12, 2017
Fixing peer review

Blinding versus anonymity
Fixing peer review #1 – double-blind

Who chooses double-blind peer review at @nature journals? @elisader et al took a look #PRC8 plllqt.it/FyVKNO

Conclusions Authors choose double-blind review more frequently when they submit to more prestigious journals, when they are affiliated with less prestigious institutions, or when they are from specific countries. The double-blind option is also linked to less successful editorial outcomes.

Elisa De Ranieri, Springer-Nature
Fixing peer review #2 – double-blind

Simon Harris, IOP Publishing
Fixing peer review #3 – signed reviews

Maria Kowalczuk, BMC
Fixing peer review #4 – signed reviews

Survey

Which reviews do authors prefer?

- Signed
- Neither

<table>
<thead>
<tr>
<th>Journal</th>
<th>Signed</th>
<th>Neither</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLOS ONE</td>
<td>150</td>
<td>117</td>
<td>267</td>
</tr>
<tr>
<td>PLOS CompBio</td>
<td>15</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>PLOS Medicine</td>
<td>8</td>
<td>1</td>
<td>9</td>
</tr>
</tbody>
</table>

*excludes first-time authors

Elizabeth Seiver, Helen Atkins
PLOS
Fixing peer review #5

Hilda Bastian
http://blogs.plos.org/absolutely-maybe/2015/05/13/weighing-up-anonymity-and-openness-in-publication-peer-review/
Fixing reporting

Checklists
Improving reporting #1 - checklists

Malcolm Macleod
doi:10.1038/nature11556
Improving reporting #1 - checklists

Findings of a retrospective, controlled cohort study of the impact of a change in Nature journals' editorial policy for life sciences research on the completeness of reporting study design and execution

Malcolm Robert Macleod, The NPQIP Collaborative group
doi: https://doi.org/10.1101/187245
This article is a preprint and has not been peer-reviewed [what does this mean?]

Abstract

Objective: To determine whether a change in editorial policy, including the implementation of a checklist, has been associated with improved reporting of measures which might reduce the risk of bias. Methods: The study protocol has been published at DOI: 10.1007/s11192-016-1964-8. Design: Observational cohort study. Population: Articles describing research in the life sciences published in Nature journals, submitted after May 1st 2013. Intervention: Mandatory completion of a checklist at the point of manuscript revision. Comparators: (1) Articles describing research in the life sciences published in Nature journals, submitted before May 2013; (2) Similar articles in other journals matched for date and topic. Primary Outcome:
Improving reporting #2 – checklists

Emily Sena,
Edinburgh
Improving reporting #3

IT WAS GETTING HARDER AND HARDER TO FIND A TRULY MEANINGFUL RELATIONSHIP AT THE MEDICAL JOURNAL HAPPY HOUR.
Improving reporting #4 – speeding up

Coming ... preprint server for medicine. Accelerate research, complement peer review, encourage sharing. @MedArXiv @YODAProject w/@OSFramework
Reasons to be cheerful?

Should we be optimistic or pessimistic?
Pessimism #1

“There seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, too obscure, and too contradictory, no analysis too self-serving, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print”

Drummond Rennie,
quoted by David Moher
Pessimism #2

Steve Goodman,
JAMA. 1966 Mar
Some Optimism? – COI declarations

Alexandra Winter
@alexandralw2

..Considerable methodological challenges to studying author conflict of interest Quinn Grundy @peerrevcongress #Prc8

Methodological challenges

- 130 different ways to state no conflicts
  - "None declared"
  - "Nothing to declare"
  - "No relevant conflicts"

- Nearly 40% of statements contained biographical information or current funding information

- Highly inconsistent and difficult to locate

Discussion

- Just under 1 in 4 biomedical articles disclose a conflict of interest

- Disclosed conflict of interest is concentrated among certain types of studies

- Consumers may be disproportionately exposed to research by authors with conflicts of interest

- Need to standardize reporting requirements
"At first, I took the stance of "who am I to challenge them", but recognized after the first review that I am the patient with the experience and perspective that can help to inform the practice of research."

Sara Schroter, BMJ
Optimism #3 – patient involvement

Fascinating approach to peer review of @PCORI grants involving patients/carers/advocates, stakeholders (eg insurers) AND scientists #PRC8

Laura Forsythe, PCORI
Optimism #4 – network of research
Optimism #5 – humour

“The difference between medical research and agricultural research is that medical research is done by doctors but agricultural research is not done by farmers.”

Attributed to M. Healy in D. Altman, SIM, 1998
Thanks for listening!

@TheoBloom
@bmj_latest
Jackie Marchington
Disclosures

• The opinions expressed in this webinar are mine, and do not necessarily reflect those of my employer.

• My employer paid for my registration and subsistence costs to attend the peer review congress, mainly to stop my unseemly pleading.
As a newbie...

• Similar size and feel to ISMPP EU meeting
• Not the usual publishers (companies) we meet at ISMPP
• Small exhibition, 16 exhibitors
  – Data/analytics
  – Workflow/back office
  – Peer review management
  – Editorial services
  – EQUATOR
Connected

• All non-keynotes research based
• Live streamed on Facebook
• Active Twitter participation
  – Questions via Twitter
• Queues at the microphones
• Simultaneous publications
• Ran pretty much to time
Bias associated with conflict of interest and peer review

Focusing on industry (me, not the agenda!)
Introductory keynote

- COIs
  - information overload
- Bias
  - Methods/research questions
  - Unpublished studies/ selective reporting
  - Analysis
  - Interpretation “spin”
Stopping spin

• Checklist for peer reviewers
• Peer review methods and results (including supp info)

• Eliminate author discussion section
• Post-publication discussion
  – Multiple discussions
  – Megaphone effect (social media)
Conflict of interest statements

COIs are confusing

• 130 different ways of stating no conflicts of interest!
• Conclusion: Conflict of interest statements should be standardized
  – No mention of ICMJE form
  – No mention of CONVEY global disclosure system
Industry bias in systematic reviews

Systematic reviews with industry funded authors are biased

• Study of studies about systematic review bias
  – Methodological quality similar
  – Statistically favourable results frequency similar
  – Financial COI = more favourable conclusions

• Unclear whether funding impacts results of systematic reviews
Study registration: missing studies

Do missing trials affect the conclusions of systematic reviews?

• Including additional trials found only on CT.gov made no difference to the strength of evidence or conclusions of systematic reviews in 5 clinical areas

• Suggested reasons for this include:
  – few of the additional studies included results
  – outcomes were mismatched between registry and paper
Interim results

• Of 171 papers reporting interim results, only 40% were prespecified

• For studies >1 year past completion date (158/171)
  – only 57% were fully (finally) reported
  – 85% of abstract conclusions did not change

• Journals should only report prespecified interim data sets and commit to publishing full results on trial completion
Spin

- Study of “spin” studies...
  - Studies more prevalent in trials
  - Spin more prevalent in trials
  - Spin not associated with industry funding

**Design:** “We had sufficient data to[…]analyse the association of industry sponsorship[…]with spin”

**Results:** “However, the meta-analysis found no significant association, possibly owing to the heterogeneity of the 7 included articles”
Data sharing: academia

- Survey of clinical trial authors
- About half had a plan and about a third had received requests
- Happy for inclusion in meta analyses, less so for replication
- 3–125 hours to prepare data set
YODA (Yale University Open Data Access) update

- 73 research proposals from 159 trials
- 89% approved, 3% under review, 8% did not proceed
  - Confidentiality
  - Non-availability of specific data elements
  - Proposal not clear

- Secondary research: 39
- Meta analysis: 35
- Validation studies: 17

- In progress: 50
- Paperwork: 8
- Submitted: 3
- Published: 2
Improving peer review and scientific publication

Registration and reporting
Quality of reporting

• COMPARE-style study
• 200 RCT publications
  – Few discrepancies in study design, type or interventions
  – Middling discrepancies in study arms and primary outcome reporting
  – Often discrepancies in start/finish dates, study sponsor, 2° outcomes and data monitoring committees

Quality of reporting (cont)

• Non-industry funding associated with lower quality reporting

Have you ever...

• had a peer review challenge specifically on a checklist item?
  - Yes
  - No
  - N/A (not part of my role)
Optimism bias

• Overestimation of treatment effect sizes (2007–17)
  – Proposed effect size ~25% greater than observed
  – Trials with a statistically significant effect proposed less optimistic effect sizes
  – Compared with 1955–2006, optimism bias has reduced

• Nearly 80% included no rationale for the proposed effect size

• Does failure to establish statistical significance mean we are missing out on incremental clinical improvements?
Registration and reporting

- Finnish ethics review board study, trial protocols approved in 2002 and 2007

Increase in registration over time:
- 61%

Registered trials more likely to be published:
- 68%
- 39%

...and with the same primary outcomes:
- 64%
- 25%
How about industry?


Table 1. Study Characteristics Associated With Prospective Registration, Publication, and Publication Without Discrepant Primary Outcomes

<table>
<thead>
<tr>
<th>Trial Characteristic</th>
<th>Clinical Trials, No. (N = 113)</th>
<th>Registered No. (%)</th>
<th>AOR (95% CI)</th>
<th>Publisheda No. (%)</th>
<th>AOR (95% CI)</th>
<th>Published Without Discrepant Primary Outcomesb No. (%)</th>
<th>AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Industry</td>
<td>53</td>
<td>46 (87)</td>
<td>1.97 (0.50-7.81)</td>
<td>36 (68)</td>
<td>1.23 (0.42-3.61)</td>
<td>33 (62)</td>
<td>1.35 (0.47-3.89)</td>
</tr>
<tr>
<td>Non-industry</td>
<td>60</td>
<td>23 (38)</td>
<td>1 [Reference]</td>
<td>28 (47)</td>
<td>1 [Reference]</td>
<td>22 (37)</td>
<td>1 [Reference]</td>
</tr>
</tbody>
</table>

Trial registration is good for results disclosure

Jackie Marchington @blazingpoodles · Sep 11
Wow, post FDAAA shows 100% registration, 100% results reporting and 99% publication rate #PRC8 for neuropsychiatric medications

View Tweet activity
A reduction in zombies...

• December 1, 2014, of 329 trials
  – 109 (33%) had results posted on ClinicalTrials.gov only,
  – 42 (13%) available from PubMed only
  – 81 (25%) available from both
  – 97 (29%) in neither

71% of trials have results disclosed
Thank You
Questions

• To ask a question, please type your query into the Q&A box

• To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question
Upcoming ISMPP U’s

- November 29, 2017
- Topic: Challenges with Review Articles
We hope you enjoyed today's presentation. Please check your email for a link to a survey that should take only a few minutes to complete. We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!